METHOD OF USING EXPANDABLE VEIN LIGATOR CATHETER HAVING MULTIPLE ELECTRODE LEADS

This application is a continuation of application Ser. No. 09/866,517, filed May 25, 2001 now U.S. Pat. No. 6,769,433, which is a continuation of Ser. No. 09/267,756 (now U.S. Pat. No. 6,237,606) filed on Mar. 10, 1999, which is a divisional of application Ser. No. 08/927,251 (now U.S. Pat. No. 6,200, 312) filed on Sep. 11, 1997, the contents of which are all hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The invention relates generally to a method and apparatus for applying energy to shrink a hollow anatomical structure such as a vein, and more particularly, to a method and apparatus using an electrode device having multiple leads for applying said energy.

The human venous system of the lower limbs consists essentially of the superficial venous system and the deep venous system with perforating veins connecting the two systems. The superficial system includes the long or great saphenous vein and the short saphenous vein. The deep venous system includes the anterior and posterior tibial veins which unite to form the popliteal vein, which in turn becomes the femoral vein when joined by the short saphenous vein.

The venous system contains numerous one-way valves for directing blood flow back to the heart. Venous valves are usually bicuspid valves, with each cusp forming a sack or reservoir for blood which, under retrograde blood pressure, forces the free surfaces of the cusps together to prevent retrograde flow of the blood and allows only antegrade blood flow to the heart. When an incompetent valve is in the flow path, the valve is unable to close because the cusps do not form a proper seal and retrograde flow of the blood cannot be stopped. When a venous valve fails, increased strain and pressure occur within the lower venous sections and overlying tissues, sometimes leading to additional valvular failure. Two venous conditions which often result from valve failure are varicose veins and more symptomatic chronic venous insufficiency.

The varicose vein condition includes dilation and tortuosity of the superficial veins of the lower limbs, resulting in unsightly discoloration, pain, swelling, and possibly ulceration. Varicose veins often involve incompetence of one or more venous valves, which allow reflux of blood within the superficial system. This can also worsen deep venous reflux and perforator reflux. Current treatments of vein insufficiency include surgical procedures such as vein stripping, ligation, and occasionally, vein-segment transplant.

Ligation involves the cauterization or coagulation of vascular lumina using electrical energy applied through an electrode device. An electrode device is introduced into the vein lumen and positioned so that it contacts the vein wall. Once properly positioned, RF energy is applied to the electrode device thereby causing the vein wall to shrink in cross-sectional diameter. A reduction in cross-sectional diameter, as for example from 5 mm (0.2 in) to 1 mm (0.04 in), significantly reduces the flow of blood through the vein and results in an effective ligation. Though not required for effective ligation, the vein wall may completely collapse thereby resulting in a full-lumen obstruction that blocks the flow of blood through the vein.

One apparatus for performing venous ligation includes a tubular shaft having an electrode device attached at the distal tip. Running through the shaft, from the distal end to the proximal end, are electrical leads. At the proximal end of the shaft, the leads terminate at an electrical connector, while at the distal end of the shaft the leads are connected to the electrode device. The electrical connector provides the interface between the leads and a power source, typically an RF generator. The RF generator operates under the guidance of a control device, usually a microprocessor.

The ligation apparatus may be operated in either a monopolar and bipolar configuration. In the monopolar configuration, the electrode device consists of an electrode that is either positively or negatively charged. A return path for the current passing through the electrode is provided externally from the body, as for example by placing the patient in physical contact with a large low-impedance pad. The current flows from the ligation device to the low impedance pad. In a bipolar configuration, the electrode device consists of a pair of oppositely charged electrodes separated by a dielectric material. Accordingly, in the bipolar mode, the return path for current is provided by the electrode device itself. The current flows from one electrode, through the tissue, and returns by way of the oppositely charged electrode.

To protect against tissue damage; i.e., charring, due to cauterization caused by overheating, a temperature sensing device is attached to the electrode device. The temperature sensing device may be a thermocouple that monitors the temperature of the venous tissue. The thermocouple interfaces with the RF generator and the controller through the shaft and provides electrical signals to the controller which monitors the temperature and adjusts the energy applied to the tissue, through the electrode device, accordingly.

The overall effectiveness of a ligation apparatus is largely dependent on the electrode device contained within the apparatus. Monopolar and bipolar electrode devices that comprise solid devices having a fixed shape and size limit the effectiveness of the ligating apparatus for several reasons. Firstly, a fixed-size electrode device typically contacts the vein wall at only one point on the circumference or inner diameter of the vein wall. As a result, the application of RF energy is highly concentrated within the contacting venous tissue, while the flow of RF current through the remainder of the venous tissue is disproportionately weak. Accordingly, the regions of the vein wall near the point of contact collapse at a faster rate then other regions of the vein wall, resulting in non-uniform shrinkage of the vein lumen. Furthermore, the overall strength of the occlusion may be inadequate and the lumen may eventually reopen. To avoid an inadequate occlusion RF energy must be applied for an extended period of time. Application of RF energy as such increases the temperature of the blood and usually results in a significant amount of heat-induced coagulum forming on the electrode and in the vein which is not desirable.

Secondly, the effectiveness of a ligating apparatus having a fixed electrode device is limited to certain sized veins. An attempt to ligate a vein having a diameter that is substantially greater than the electrode device can result in not only non-uniform shrinkage of the vein wall as just described, but also insufficient shrinkage of the vein. The greater the diameter of the vein relative to the diameter of the electrode device, the weaker the energy applied to the vein wall at points distant from the point of contact. Accordingly the vein wall is likely to not completely collapse prior to the venous tissue becoming over cauterized at the point of electrode contact. While coagulation as such may initially occlude the vein, such occlusion may only be temporary in that the coagulated blood may eventually dissolve and the vein partially open. One solution for this inadequacy is an apparatus having inter-